SALMONELLA RAPID LATEX TEST KIT

For professional *in Vitro* diagnostic use only

Latex slide agglutination test for the confirmatory identification of presumptive Salmonella colonies

INTENDED USE
Salmonella Rapid Latex Test Kit is a manual latex slide agglutination test for the qualitative confirmatory identification of presumptive Salmonella colonies cultivated on selective agar plates.

PRINCIPLE OF THE TEST
Latex particles are coated with polyvalent antisera raised against a wide range of Salmonella antigens. When mixed with a suspension of Salmonella organisms, the latex particles rapidly agglutinate to form visible clumps**.**

REAGENTS AND MATERIALS PROVIDED
REAG TEST S1: Salmonella Latex Reagent: 2.5 mL- Latex particles coated with rabbit antiserum against Salmonella antigens. Preserved with 0.099% sodium azide. (dropper red cap)
CONTROL +: positive Control: 0.5mL-Inactivated preparation of Salmonella antigens preserved with 0.099% sodium azide. (dropper white cap)
SAMPLE DILUENT: 0.9% Isotonic Saline: 5.0mL-Preserved with 0.095% sodium azide. (*yellow* cap)
DISPOSABLE AGGLUTINATION CARDS (SLIDE) : 10 cards, each with 6 black agglutination areas
MIXING STICKS (2x25) : 50 disposable mixing sticks
DISPOSABLE PIPETTE: 1 disposable transfer pipette
INSTRUCTIONS FOR USE

MATERIALS REQUIRED BUT NOT SUPPLIED
Bacteriological loops
Selective culture medium for Salmonella isolation
Timer

WARNINGS AND PRECAUTIONS
Safety:
- The reagents supplied in this kit are for in vitro diagnostic use only
- The kit is intended for professional use only.
- Sodium azide, which is used as a preservative in the kit reagents can react with lead or copper plumbing to form potentially explosive metal azides. Dispose by flushing with a large volume of water to prevent azide build-up.
- Appropriate precautions should be taken when handling or disposing of potential pathogens. Decontamination of infectious material can be achieved with sodium hypochlorite at a final concentration of 3% for 30minutes. Liquid waste containing acid must be neutralised before treatment.
- The positive control has been inactivated during the manufacturing process. However, it should be handled as though potentially infectious.

Procedural:
- Salmonella Rapid Latex Test Kit should be used according to the kit instructions.
- Allow all reagents to reach room temperature before use.
- Do not dilute any of the kit reagents
- Do not intermix reagents from different batches of kits.
- Do not freeze any of the kit reagents
- Do not allow the latex reagent dropper to touch the positive control or bacterial samples.
- Be careful only to record agglutination. Reactions that are “curdy” or “stringy” may not be true agglutination.
- Ensure the slide is clean and dry prior to use.

STORAGE AND SHELF LIFE
Salmonella Rapid Latex Test Kit should be stored at 2-8°C when not in use. The kit should not be used after the expiry date printed on the label.

SPECIMENS
The sample consists of colonies isolated on a selective agar medium.

TECHNIQUE
Quality Control:
The following controls should be performed each time the kit is used.
1-Reagent Control: Add one drop of REAG TEST S1 to one drop of SAMPLE DILUENT (using pipette) in the same circle on a slide. Mix and spread the liquid over the entire area of the circle with a mixing stick. Rock the slide gently for 2 minutes and observe for agglutination. If any agglutination is seen, either the latex or the saline is contaminated and should be discarded.
2-Positive Control: Add one drop of CONTROL+ to one circle on the test slide. Add one drop of REAG TEST S1 to the same circle and mix. Do not allow the dropper to touch the positive control. Rock the slide gently. Within 2 minutes, agglutination, indicating a positive result, should be visible. If no agglutination is seen, a fresh kit should be used**.**

Test Procedure:
1. Dispense 1 drop SAMPLE DILUENT (using pipette) into a circle of an agglutination slide.
2. Using an inoculating loop, remove a colony from the selective agar plate and emulsify the colony in the drop of SAMPLE DILUENT to produce a heavy smooth suspension. Suspensions should only be made from colonies with morphologies resembling Salmonella spp.
3. Rock the slide gently for up to 2 minutes and observe for autoagglutination or clumping. If the suspension remains smooth, proceed to Step 4 (see Limitations of Use Note 1).
4. Mix the REAG TEST S1 by gently inverting and add one drop near to the bacterial suspension. Do not allow the dropper to touch the suspension.
5. Mix the latex reagent and the bacterial suspension with a clean mixing stick and rock the slide gently two or three times. Excessive rocking of the slide is not necessary. Examine for agglutination within a maximum of 2 minutes.

6. After reading, discard the used mixing sticks and slides into suitable disinfectant.

INTERPRETATION
Agglutination within 2 minutes is a positive result and indicates the presence of Salmonella in the sample. Absence of agglutination indicates that Salmonella is not present in the test culture.

LIMITATIONS OF USE
1. Results should be interpreted in the context of all available clinical and laboratory information.
2. Rough strains of Salmonella are known to cause non-specific autoagglutination in saline alone and therefore cannot be tested with Salmonella Rapid Latex Test Kit.
3. Some non-motile strains may not be detected by Salmonella Rapid Latex Test Kit.
4. Some oxidase-positive organisms may give false positive reactions.
5. Old stock cultures of Enterobacteriaceae on nutrient agar slopes may cause non-specific agglutination whereas old stocks of Salmonella may give false negative results.
6. Identification with Salmonella Rapid Latex Test Kit is presumptive and all positive results should be confirmed by further identification tests and serotyping of pure cultures.

PERFORMANCE CHARACTERISTICS
Salmonella Rapid Latex Test Kit has been evaluated in comparison with a well-established commercially available latex agglutination test for Salmonella. 126 isolates of Salmonella spp. and a range of 58 potentially cross-reacting bacteria were tested in both products**.**

		Salmonella Rapid Latex Test Kit		
		+ve	-ve	Total
Commercial Latex Test	+ve	135**	1*	136
	-ve	0	48***	48
	Total	135	49	184

Sensitivity: 135/136 = 99.3%
Specificity: 48/48 = 100%
Concordance: 183/184 = 99.5%

*1 sample was negative in Salmonella Rapid Latex Test Kit but equivocal in the commercial test. This sample was subsequently identified as Salmonella bergen.
** Of the 135 isolates in this group, 11 were cross reactants in both tests. These were isolates of *C. diversus* (1), *A. baimannii* (2), *P. stuartii* (1), *B. cereus* (2), *S.aureus* (4), *Strep spp* (1)
However all of the above either did not grow or showed very atypical morphologies, when cultured on Salmonella-selective media. In the case of B. cereus, agglutination was atypical (stringy)
*** 1 *S. dublin* was repeatedly negative in both tests.

REPRODUCIBILITY
Intra-batch reproducibility was evaluated by testing sensitivity and specificity of 1 batch of product against serial dilutions of reference and kit control antigens, and a panel of 34 bacterial samples. Different operators carried out tests on 3 separate occasions. End-point titres obtained with reference/control antigens and qualitative results with the panel were identical in the three assays.
Inter-batch reproducibility was examined by testing sensitivity and specificity of 3 batches of product against serial dilutions of reference and kit control antigens, and a panel of 34 bacterial samples. Between the 3 batches, variation in end-point titres was minimal (1 doubling dilution) and qualitative results with the panel correlated 100%.

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT (50 tests) **REF 271030**

REAG TEST S1:	2.5 mL (dropper red cap)
CONTROL +:	0.5 mL (dropper white cap)
SAMPLE DILUENT	5.0 mL (*yellow* cap)
DISPOSABLE AGGL. CARDS (SLIDE)	10 cards with 6 wells each
MIXING STICKS:	2x25 disposable mixing sticks
DISPOSABLE PIPETTE:	1 disposable transfer pipette
INSTRUCTIONS FOR USE	1 item

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